

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)
COMPOUNDING PHARMACY, INC.) MDL No. 2419
PRODUCTS LIABILITY LITIGATION) Dkt. No. 1:13-md-2419-FDS
_____))
This Document Relates to:)
All Cases)

AFFIDAVIT OF JOHN W. CULCLASURE, M.D.

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

Comes John W. Culclasure, M.D., after first being duly sworn, and states as follows:

1. I am over 18 years of age, have personal knowledge of the facts contained herein, and am competent to testify to same.

2. I am currently a licensed physician, and I was licensed as a physician during all times relevant hereto. I am currently the Medical Director at Saint Thomas Outpatient Neurosurgical Center, LLC, and I was the Medical Director at Saint Thomas Outpatient Neurosurgical Center, LLC, at all times relevant hereto.

3. Based on review of available records, I administered epidural steroid injections, as part of the medical treatment and health care provided to the following Plaintiffs:

Robert Barnard	Terry Pierce
Dennis O'Brien	Cindy Carman
Gayla Gobble	Jerry Demps
Herman Mathias	Michelle Minor
Elizabeth Pruitt	Margaret White
Marie Hester	Vickie Barger
Lisa Maddox	Orval Wayne McWhorter
Samuel Groves	Betty Smiley
John Edward Jones	Angela May
Gary Wayne Waddey	

4. Based on review of available records, a different physician at Saint Thomas Outpatient Neurosurgical Center, LLC, administered epidural steroid injections as part of the medical treatment and health care provided to the following Plaintiffs:

Fredia Berry	John Alexander
Randy Davis	Reba Temple
Tracey Privitte (Siler)	Ella Mae Redkevitch
Joan Peay	

5. Plaintiff Martha Schulz received an epidural steroid injection at Saint Thomas Outpatient Neurosurgical Center, LLC in 2011, before methylprednisolone acetate from the three (3) contaminated lots compounded by New England Compounding Center was received.

6. On September 7, 2012, I performed a medial branch block injection on Plaintiff Claudia Ellis. Ms. Ellis received an injection of 0.5 ml of 1:1 mix of pf .75% Bupivacaine + pf 4% Lidocaine.

7. Ms. Ellis did not receive New England Compounding Center preservative-free methylprednisolone acetate from one of the three recalled lots.

8. During an epidural steroid injection, the patient's vital signs are monitored. The patient is placed prone and, utilizing aseptic technique, the injection site is prepped. I use C-arm fluoroscopy to identify the site for needle placement. I then direct the needle to the target area and confirm the needle location utilizing contrast dye and the C-arm fluoroscopy. Once needle location is confirmed, I administer the steroid and monitor the patient's tolerance.

9. The procedure I have described for an epidural steroid injection complies with the accepted standard of care for those procedures in this community. I am familiar with that standard of care based on my education, training, and experience, and particularly on my experience practicing as a physician in the Nashville medical community performing such injections in 2012.

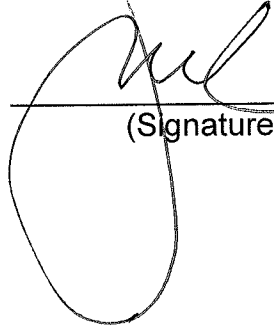
10. At Saint Thomas Outpatient Neurosurgical Center, LLC, only licensed physicians perform epidural steroid injections.

11. At Saint Thomas Outpatient Neurosurgical Center, LLC, spinal epidural steroid injections are performed on patients following a diagnosis of, and as treatment and care for, pain related to spinal nerves.

12. In June of 2011, I, along with Debra Schamberg, R.N., made the decision to purchase preservative-free methylprednisolone acetate from the New England Compounding Center for Saint Thomas Outpatient Neurosurgical Center, LLC.

13. Saint Thomas Outpatient Neurosurgical Center, LLC, is currently licensed as an ambulatory surgery center, and it was licensed as an ambulatory surgery center during all times relevant hereto.

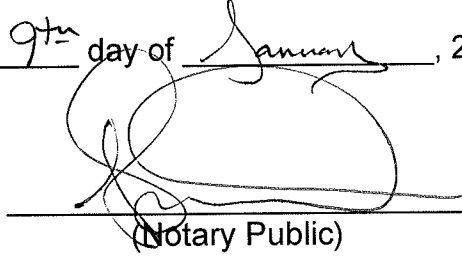
14. Saint Thomas Outpatient Neurosurgical Center, LLC, through the health care providers working there, provides health care services to patients, including the provision of care to the Plaintiffs in this case.


(Signature of Affiant)

STATE OF TENNESSEE)
)
COUNTY OF Davidson)

Sworn to and subscribed by me on this 9th day of January, 2014.




(Notary Public)

My Commission Expires Commission Expires MAY 20, 2014